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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/826,925	HERUTH ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-56 and 83-99* is/are pending in the application.

4a) Of the above claim(s) *44 and 99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-38,40-43,45-56 and 83-98* is/are rejected.

7)☒ Claim(s) *39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/15/09, 2/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Indicated allowability of the claims has been regretfully withdrawn. Prosecution on the merits of this application is reopened on claims considered unpatentable because the claims are considered to be anticipated by US Patent Application Publication No. 2004/0002742 or unpatentable over that publication in view of another or other reference(s). See the rejections set forth below for details.

Information Disclosure Statement

The information disclosure statements filed 11/15/09 and 2/13/09 have been considered.

Claim Objections

Claims 86 and 97 is objected to because of the following informalities:

On line 3 of claim 86, "each of the signals" should be replaced with "signals from each accelerometer".

On line 1 of claim 97, "further comprising a medical device" should be deleted because the medical device is already recited in claim 83. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-26, 30, 33, 35, 38, 41, 43, 45, 48, and 49 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US Patent Application Publication No. 2004/0002742 to Florio. Regarding claim 24, Florio teaches a medical system comprising a medical device 100 that delivers therapy to a patient (see entire document, especially paragraphs 31, 36 of Florio) and monitors at least one physiological parameter based on a signal received from at least one sensor (see entire document, especially paragraphs 33-35 of Florio). A processor determines a value of a metric indicative of sleep quality based on values of the physiological parameter determined during delivery of the therapy by the medical device according to a therapy parameter set and associates the sleep quality metric value with the therapy parameter set (see

entire document, especially paragraphs 35, 36, 56-70 of Florio), wherein an evaluation of how a therapy parameter set effects the sleep quality (disturbance) metric is an association of the two. A memory 260 receives the sleep quality metric value (see entire document, especially paragraphs 45, 60 of Florio) and an indication of the therapy parameter set associated with the sleep quality metric value (see entire document, especially paragraphs 43, 67, 69 of Florio).

Regarding claim 25, the medical device monitors at least activity level (see entire document, especially paragraphs 33-35, 57-61 of Florio), posture (see entire document, especially paragraph 47 of Florio), or respiration rate (see entire document, especially paragraphs 46, 52 of Florio).

Regarding claim 26, the medical device monitors blood oxygen saturation of partial pressure of oxygen within blood (see entire document, especially paragraph 67 of Florio).

Regarding claim 30, the processor identifies when the patient is asleep (Rest) and identifies at least one of a number of arousal events and a number of apnea events during a sleep period as the value of the sleep quality metric (see entire document, especially paragraphs 33-35. 57-60 of Florio).

Regarding claim 33, the processor determines a value of each of a plurality of sleep quality metrics (see entire document, especially paragraphs 34, 60 of Florio) and determines a value of an overall sleep quality metric based on the plurality of sleep quality metric values (see entire document, especially paragraph 35 of Florio).

Regarding claim 35, a programming device is included to present sleep quality information to a user based on the sleep quality metric values determined by the processor (see entire document, especially paragraph 70 of Florio).

Regarding claims 38 and 41, the processor determines a plurality of values of the sleep quality metric over time (see entire document, especially paragraphs 33-36, 60-63 of Florio) , each of the values of the sleep quality metric determined based on values of the at least one physiological parameter that were determined during deliver of therapy according to at least one of the plurality of therapy parameter sets (see entire document, especially paragraphs 33, 34, 59 of Florio), and associates each of the determined values of the sleep quality metric with the at least one of the plurality of therapy parameter sets (see entire document, especially paragraph 36, 63-70 of Florio). For each of the plurality of therapy parameter sets, the processor determines a representative value of the sleep quality metric based on the values of the sleep quality metric associated with the therapy parameter set (see entire document, especially paragraph 35, 68 of Florio).

Regarding claim 43, the processor comprises a processor of the medical device (see entire document, especially paragraph 37 of Florio).

Regarding claim 45, the medical device comprises an implantable medical device (see entire document, especially fig. 1; paragraph 17 of Florio).

Regarding claim 48, Florio teaches a medical system comprising means for monitoring, means for determining, means for identifying, and means for associating, as claimed (see entire document, especially figs. 1, 2; paragraphs 30, 33, 46, 52, 55-71 of

Florio). As to the language "means for monitoring at least one physiological parameter of a patient", "means for determining a value of a metric that is indicative of sleep quality based on the at least one physiological parameter", "means for identifying a current therapy parameter set used by a medical device to delivery therapy to the patient", and "means for associating the sleep quality metric value with the current therapy parameter", each phrase meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph.

The corresponding structure set forth in the instant specification for the "means for monitoring at least one physiological parameter of a patient" is merely an implantable medical device or portion thereof and/or sensor(s) that collects physiological parameter information (see p. 12 of the instant specification). Florio discloses an implantable medical device that acquires physiological parameter information (see entire document, especially figs. 1, 2; paragraphs 30, 33, 46, 52 of Florio).

The corresponding structure set forth in the instant application for "means for determining a value of a metric that is indicative of sleep quality based on the at least one physiological parameter" is merely an implantable medical device, or portion thereof that determines a value of a sleep quality metric (see p. 15 of the instant specification). Florio teaches such an implantable medical device, or portion thereof, that determines sleep quality metric value based on a measured physiological parameter (see entire document, especially paragraphs 55-63 of Florio).

The corresponding structure set forth in the instant application for "means for identifying a current therapy parameter set used by a medical device to delivery therapy to the patient" and ""means for associating the sleep quality metric value with the current therapy parameter set" is merely an implantable medical device, or portion thereof that identifies a current therapy set and associates the sleep quality metric value with the current therapy parameter set (see pp. 15-16 of the instant application). Florio discloses an implantable device identifying a current therapy parameter set and associating the sleep quality metric value with the current therapy parameter set (see entire document, especially paragraphs 36, 63-70 of Florio). In particular, a portion 240 of the implantable medical device 100 analyzes the current and previous therapies to evaluate how each therapy affects the sleep disturbance metrics, wherein the sleep disturbance metrics are metrics indicative of sleep quality (see entire document, especially fig. 2; paragraphs 36, 69-71 of Florio), wherein such analysis and evaluation is a association of the sleep quality metric and the current therapy parameter set.

With regard to claim 49, "means for determining a plurality of values of the sleep quality metric over time" and "means for presenting sleep quality information to a user based on the plurality of values", the language meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure set forth in the instant specification for "means for determining a plurality of values of the sleep quality metric over time" is merely an implantable medical device of portion thereof that determines a plurality of values of the sleep quality metric over time (see p. 14 of the instant application). Florio discloses such an implantable medical

device performing such a function (see entire document, especially paragraphs 17, 33-35, 55-61, 68 of Florio). The corresponding structure set forth in the instant specification for "means for presenting sleep quality information to a user based on the plurality of values" is merely a programmer that presents the sleep quality information to a user (see page 14 of the instant application). Florio discloses such a programmer (see entire document, especially paragraph 70 of Florio).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 2005/0085738 to Stahmann et al. (Stahmann '738). Regarding claims 27 and 29, Florio lacks the sleep quality metric comprising sleep efficiency. However, Stahmann '738 teaches using sleep efficiency as a measure of sleep quality, wherein the processor identifies when the patient is attempting to sleep and when the patient is asleep, and determines a percentage of time that the patient is asleep while the patient is attempting to sleep as the value of the sleep quality metric (see entire document, especially paragraphs 168-175, 185-188 of Stahmann '738). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of invention to use sleep efficiency, as determined by Stahmann '738, as the sleep quality metric of Florio, as it would merely be the substitution of one known sleep quality metric for another.

Regarding claim 31, the processor identifies when the patient is within a sleep state (see entire documents, especially paragraph 57 of Florio; paragraphs 170, 171 of Stahmann '738) and determines an amount of time that the patient was within the sleep state (see entire document, especially paragraph 171 of Stahmann '738).

Claims 28, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 2005/0143617 to Auphan. Regarding claim 28, Florio lacks the sleep quality metric comprising sleep latency. However, Auphan discloses that sleep latency (time to fall asleep) is a sleep quality metric and further shows its determination by identifying a first time at which the patient begins attempting to fall asleep and a second time when the patient falls asleep (see entire document, especially paragraphs 24, 56 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use sleep latency, as described by Auphan as the sleep quality metric of Florio, as it would merely be the substitution of one known sleep quality metric for another.

Regarding claims 33, and 34, Florio lacks applying a weight factor. However, Auphan teaches a sleep quality index to indicate sleep quality, wherein the index is a value of an overall sleep quality metric based on a plurality of sleep quality metric value

and a weighting factor is applied to at least one value to determine the sleep quality index (see entire document, especially paragraph 58 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sleep quality index described by Auphan as the sleep quality metric of Florio, as it would merely be the substitution of one known sleep quality metric for another.

Claim 32 is rejected under 35 .S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 2005/0038745 (Stahmann '745) and US Patent Application Publication NO. 2005/0065560 to Lee et al. (Lee '560). Florio lacks the sleep state being an S3 or S4 sleep state. However, Stahmann '745 teaches determining the duration of non-REM sleep states as an indication of sleep quality (see entire document, especially paragraph 47 of Stahmann '745). Further Lee '560 discloses that data about sleep states 3 and 4 are useful for sleep quality assessment because the most restful sleep occurs in those states (see entire document, especially paragraph 73 of Lee '560). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use information about the duration of sleep state S3 or S4 as the sleep quality metric or part of the sleep quality metric of Florio, as it would merely be the substitution of one know sleep quality metric for another.

Claims 36 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 37, 51, 52, and 54 below, and

further in view of US Patent No. 6,273,856 to Sun et al. Regarding claims 36 and 53, Florio, as modified, teaches presenting the information in tabular form (see entire document, especially fig. 3 of Stahmann '738) rather than as a trend diagram, histogram, or pie chart. However, Sun teaches that data may equally be displayed as a histogram or tabular listing (see entire document, especially col. 5, lines 43-51 of Sun). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to present the information in the form of a histogram in the programmer of Florio, as modified, since Sun shows the histogram and table to be functionally equivalent for presenting data.

Claims 37, 51, 52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 2005/0085738 to Stahmann (Stahmann '738). Regarding claim 51, Florio teaches the external programming device receiving the sleep quality metric values and indications of therapy parameter sets with which the metric values are associated from the implantable medical device but lacks further details as to the external programming device. However, Stahmann '738 teaches an external programming device including a display wherein the device presents information obtained, including sleep quality information, from the implantable medical device to a user via the display (see entire document, especially fig. 23; paragraphs 157, 159, 189, 190 of Stahmann '738). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use

the external programming device of Stahmann '738 as that of Florio or to combine it with that of Florio, as it would merely be the substitution of one known external programming device for another or since Florio teaches using a programmer to perform analysis of the downloaded information and Stahmann '738 discloses an appropriate such programmer allowing such analysis.

Regarding claim 52, the programming device presents a graphical representation of the sleep quality metric values via the display, wherein any visual representation of such values is a graphic representation.

Regarding claims 37 and 54, the programming device presents a message related to sleep quality based on the sleep quality metric values, wherein the message is information regarding sleep quality metric values and indications of therapy parameter sets with which the metric values are associated, which are displayed by the programming device. As to the user, the applicants should note that "to a user" is merely "intended use" language which fails to define over the prior art, since Florio, as modified, teaches all of the claimed structural limitations and their recited relationships. The programming device of Florio, as modified, is certainly capable of presenting information to any user, including a patient.

Claims 40, 42, 50, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 2004/0199217 to Lee et al. (Lee '217) Regarding claims 40 and 42, Florio teaches a programming device

to present sleep quality metric information to a user (see entire document, especially paragraph 70 of Florio) but lacks further details as o the programming device. However, Lee '217 teaches an external programming device wherein metric values are presented to a user in the form of a list and allows the information to be listed in order of the metric values (see entire document, especially fig. 1; paragraphs 62, 63 of Lee '217). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the list and ability to order the list of Lee '217 in the programmer of Florio as it would facilitate comparison of therapy sets and quick therapy selection by the clinician (see entire document, especially paragraph 63 of Lee' 217).

Regarding claim 50, the language "means for determining a plurality of values of the sleep quality metric over time", "means for associating each of the determined values of the sleep quality metric with a current therapy set", "means for determining a representative value of the sleep quality metric for each of a plurality of therapy parameter sets based on the values of the sleep quality metric associated with the therapy parameter set", "means for presenting a list of therapy parameter sets and the associated representative values to a user", and "means for ordering the list of therapy parameter sets according to the associated representative values" meet the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph.

The corresponding structure set forth in the instant specification for "means for determining a plurality of values of the sleep quality metric over time" is merely an implantable device, portion thereof, or processor which determines a plurality of sleep quality metric values over time (see p. 20 of the instant specification). Florio, as

modified, teaches such an implantable device or processor (see entire document, especially paragraphs 34, 35, 59, 60 of Florio).

The corresponding structure set forth in the instant specification for "means for associating each of the determined values of the sleep quality metric with a current therapy set" is merely an implantable device, portion thereof that associates each determines sleep quality metric value with a current therapy set (see pp. 14, 15 of the instant specification). Florio, as modified, teaches such an implantable device (see entire document, especially paragraphs 36, 63-70 of Florio).

The corresponding structure set forth in the instant specification for "means for determining a representative value of the sleep quality metric for each of a plurality of therapy parameter sets based on the values of the sleep quality metric associated with the therapy parameter set" is merely an implantable device, portion thereof, or processor that determines an overall or representative value of the sleep quality metric for each of a plurality of therapy parameters sets (see p. 20 of the instant specification). Florio, as modified, teaches such an implantable device of processor (see entire document, especially paragraphs 35, 36 of Florio), wherein the count is the overall or representative value.

The corresponding structure set forth in the instant specification for "means for presenting a list of therapy parameter sets and the associated representative values to a user" is merely a display for showing a list of therapy and representative values (see p. 27 of the instant specification). Florio, as modified, teaches such a display (see entire document, especially fig. 1; paragraphs 62, 63 of Lee '217)

The corresponding structure set forth in the instant specification for "means for ordering the list of therapy parameter sets according to the associated representative values" is merely an external programmer that presents the order of therapy sets to the user on the display according to the associated representative value (see p. 27 of the instant specification). Florio, as modified, teaches such a programmer (see entire document, especially paragraphs 62, 63 of Lee '217).

Regarding claim 55, a representative value of the sleep quality metric is determined for each of the plurality of therapy parameter sets based on the values of the sleep quality metric associated with the sets (see entire document, especially paragraphs 35, 60, 61 of Florio).

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio, as applied to claims 24-26, 30, 33, 35, 38, 43, 45, 48, and 49 above, and further in view of US Patent Application Publication No. 205/0061320 to Lee et al. (Lee '320). Regarding claims 46 and 47, Florio teaches the medical device being an implantable medical device, such as a cardiac device. However, Lee '320 teaches a system which determines values of a sleep quality metric to assess and/or adjust therapy wherein therapy device may be any of a cardiac device, implantable/trial drug delivery device, or implantable/trial neurostimulator (see entire document, especially paragraphs 44, 46, 54, 57, 80, 8, 101, 118, 148, 188, 192-194 of Lee '320). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the drug pump or neurostimulator of Lee '320 as the medical device of Florio, since

Lee '320 teaches that a cardiac device, drug pump, or neurostimulator may be used for an evaluation of therapy against sleep quality, and it would merely be the substitution of one known therapy for another.

As to the term "trial" in claim 47, the neurostimulator and/or drug delivery device is capable of being used on a trial basis.

Claim 56 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 37, 51, 52, and 54 above, and further in view of US Patent Application Publication No. 205/0061320 to Lee et al. (Lee '320). Florio, as modified, teaches the medical device being an implantable medical device, such as a cardiac device. However, Lee '320 teaches a system which determines values of a sleep quality metric to assess and/or adjust therapy wherein therapy device may be any of a cardiac device, implantable/trial drug delivery device, or implantable/trial neurostimulator (see entire document, especially paragraphs 44, 46, 54, 57, 80, 8, 101, 118, 148, 188, 192-194 of Lee '320). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the drug pump or neurostimulator of Lee '320 as the medical device of Florio, as modified, since Lee '320 teaches that a cardiac device, drug pump, or neurostimulator may be used for an evaluation of therapy against sleep quality, and it would merely be the substitution of one known therapy for another.

Claims 83-85, 89, 91, 93, 94, and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 37, 51, 52, and 54 above. Regarding claims 83 and 91, Florio, as modified lacks the sleep quality metric comprising sleep efficiency. However, Stahmann '738 teaches using sleep efficiency as a measure of sleep quality, wherein the processor identifies when the patient is attempting to sleep and when the patient is asleep, and determines a percentage of time that the patient is asleep while the patient is attempting to sleep as the value of the sleep quality metric (see entire document, especially paragraphs 168-175, 185-188 of Stahmann '738). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use sleep efficiency, as determined by Stahmann '738, as the sleep quality metric of Florio, as modified, as it would merely be the substitution of one known sleep quality metric for another, wherein therapy is not delivered until the patient is determined to be asleep (at rest; see entire document, especially paragraphs 57, 58, and 62 of Florio).

Regarding claim 84, the processor receives an indication from the patient that the patient is attempting to sleep (see entire document, especially paragraphs 129, 170 of Stahmann '738).

Regarding claim 85, the processor monitors posture of the patient based on at least one signal and identifies when the patient is attempting to sleep by identifying when the patient is recumbent (see entire document, especially paragraphs 129, 169 of Stahmann '738).

Regarding claim 89, the processor identifies when the patient is asleep based on activity level (see entire document, especially paragraph 57 of Florio).

Regarding claim 93, a programming device presents sleep quality information to a user based on the sleep quality metric values (see entire document, especially paragraph 70 of Florio).

Regarding claims 94 and 96, the programming device presents a graphical representation of the sleep quality metric values via the display, wherein any visual representation of such values is a graphic representation or message.

Regarding claim 96, the limitations as to the user are merely "intended use" language which cannot be relied upon to define over the prior art, since Florio, as modified, teaches all of the claimed structural features and their recited relationships. The display of the programmer of Florio, as modified, can certainly be shown to any user, including a patient.

Regarding claim 97, the processor comprises a processor of the medical device (see entire document, especially paragraphs 30, 37 of Florio).

Regarding claim 98, the medical device comprises an implantable medical device (see entire document, especially paragraph 17; fig. 1 of Florio).

Claims 83-85, 89, 92-94, and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 37, 51, 52, and 54 above, and further in view of US Patent Application Publication No. 2005/0143617 to Auphan. Regarding claim 83 and 92, Florio, as modified, lacks the sleep quality metric

comprising sleep latency. However, Auphan discloses that sleep latency (time to fall asleep) is a sleep quality metric and further shows its determination by identifying a first time at which the patient begins attempting to fall asleep and a second time when the patient falls asleep (see entire document, especially paragraphs 24, 56 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use sleep latency, as described by Auphan as the sleep quality metric of Florio, as modified, as it would merely be the substitution of one known sleep quality metric for another, wherein therapy is not delivered until the patient is determined to be asleep (at rest; see entire document, especially paragraphs 57, 58, and 62 of Florio).

Regarding claim 89, the processor identifies when the patient is asleep based on activity level (see entire document, especially paragraph 57 of Florio).

Regarding claim 93, a programming device presents sleep quality information to a user based on the sleep quality metric values (see entire document, especially paragraph 70 of Florio).

Regarding claims 94 and 96, the programming device presents a graphical representation of the sleep quality metric values via the display, wherein any visual representation of such values is a graphic representation or message.

Regarding claim 96, the limitations as to the user are merely "intended use" language which cannot be relied upon to define over the prior art, since Florio, as modified, teaches all of the claimed structural features and their recited relationships. The display of the programmer of Florio, as modified, can certainly be shown to any user, including a patient.

Regarding claim 97, the processor comprises a processor of the medical device (see entire document, especially paragraphs 30, 37 of Florio).

Regarding claim 98, the medical device comprises an implantable medical device (see entire document, especially paragraph 17; fig. 1 of Florio).

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 83-85, 89, 91, 93, 94, and 96-98 above, and further in view of US Patent Application Publication No. 2001/0049471 to Suzuki et al. Florio, as modified, is silent as to the details of the posture sensor/accelerometer. However, Suzuki teaches a posture sensor comprising orthogonally aligned accelerometers wherein the processor identifies when the patient is recumbent based on a DC component of each of the signals (see entire document, especially paragraphs 73-75 of Suzuki). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the posture sensor of Suzuki as that of Florio, as modified, since Florio, as modified, teaches using a posture sensor and Suzuki describes an appropriate such sensor.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 83-85, 89, 91, 93,94, and 96-98 above, and further in view of US Patent Application Publication No. 2004/0215269 to Burnes et al. Florio, as modified, lacks identifying when the patient is attempting to sleep based on an activity level of the patient. However, Burnes teaches identifying when the patient is

attempting to sleep based on an activity level of the patient (see entire document, especially paragraph 39 of Burnes). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the means and method of identifying when a patient is attempting to sleep of Burnes as that of Florio, as modified, as it would merely be the substitution of one known means and method for determining when the patient is attempting to sleep for another.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738 , as applied to claims 83-85, 89, 91, 93, 94, and 96-98 above and further in view of US Patent Application Publication No. 2005/0080463 to Stahmann et al. (Stahmann '463). Florio, as modified, lacks identifying when the patient is asleep based on any of the parameters listed in claim 90. However, Stahmann '463 teaches determining the onset of sleep based on muscular activity (EMG; see entire document, especially paragraph 42 of Stahmann '463). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the detection of sleep onset of Stahmann '463 as that of Florio, as modified, as it would merely be the substitution one known sleep onset detection for another.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Stahmann '738, as applied to claims 83-85, 89, 91, 93, 94, and 96-98 below, and further in view of US Patent No. 6,273,856 to Sun et al. Regarding claims claim 95, Florio, as modified, teaches presenting the information in tabular form (see entire document, especially fig. 3 of Stahmann '738) rather than as a trend diagram, histogram, or pie chart. However, Sun teaches that data may equally be displayed as a histogram or tabular listing (see entire document, especially col. 5, lines 43-51 of Sun). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to present the information in the form of a histogram in the programmer of Florio, as modified, since Sun shows the histogram and table to be functionally equivalent for presenting data.

Allowable Subject Matter

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 39, the primary reason for allowance is the inclusion of the representative value for each therapy parameter set comprising a mean or median

value, in combination with all of the other limitations of the claim, which is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/

Primary Examiner, Art Unit 3735